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09/630,454	08/02/2000	Hungming J. Liaw	1533.0730001/SRL/TBB	9071

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EXAMINER

DEVI, SARVAMANGALA J N

ART UNIT	PAPER NUMBER
1645	9

DATE MAILED: 11/05/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No. <b>09/630,454</b>	Applicant(s) <b>Liaw et al.</b>	
Examiner <b>S. Devi, Ph.D.</b>	Art Unit <b>1645</b>	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE three MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

1)  Responsive to communication(s) filed on Aug 19, 2002.

2a)  This action is FINAL.      2b)  This action is non-final.

3)  Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

### Disposition of Claims

4)  Claim(s) 1-23 is/are pending in the application.

4a) Of the above, claim(s) 1-5, 10, and 17-23 is/are withdrawn from consideration.

5)  Claim(s) \_\_\_\_\_ is/are allowed.

6)  Claim(s) 6-9 and 11-16 is/are rejected.

7)  Claim(s) \_\_\_\_\_ is/are objected to.

8)  Claims \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

9)  The specification is objected to by the Examiner.

10)  The drawing(s) filed on \_\_\_\_\_ is/are a)  accepted or b)  objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)  The proposed drawing correction filed on \_\_\_\_\_ is: a)  approved b)  disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)  The oath or declaration is objected to by the Examiner.

### Priority under 35 U.S.C. §§ 119 and 120

13)  Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)  All b)  Some\* c)  None of:

1.  Certified copies of the priority documents have been received.
2.  Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3.  Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\*See the attached detailed Office action for a list of the certified copies not received.

14)  Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

a)  The translation of the foreign language provisional application has been received.

15)  Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

### Attachment(s)

1)  Notice of References Cited (PTO-892)

4)  Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_

2)  Notice of Draftsperson's Patent Drawing Review (PTO-948)

5)  Notice of Informal Patent Application (PTO-152)

3)  Information Disclosure Statement(s) (PTO-1449) Paper No(s). 2 & 3.

6)  Other:

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## **DETAILED ACTION**

### **Election**

1) Acknowledgment is made of Applicants' election with traverse of invention I, claims 6-16, and of the bacterial species *Corynebacterium* and the amino acid species lysine, filed 08/19/02 (paper no. 7) in response to the restriction mailed 06/25/02 (paper no. 5). Because Applicants did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (M.P.E.P § 818.03(a)).

### **Status of Claims**

2) Claims 1-23 are pending.

Claims 1-5 and 17-23 are withdrawn from consideration as being directed to non-elected inventions. See 37 C.F.R 1.142(b) and M.P.E.P § 821.03. Claim 10 encompassing a non-elected species is currently withdrawn from consideration.

Claims 6-16 have been elected.

Claims 6-9 and 11-16 are under examination. A First Action on the Merits is issued for these claims.

### **Priority**

3) The instant application claims domestic priority to the provisional application, SN 60/146,350, filed 08/02/1999.

### **Information Disclosure Statements**

4) Acknowledgment is made of Applicant's Information Disclosure Statements filed 11/15/00 and 03/09/01 (paper no. 2 and 3). The information referred to therein has been considered and a signed copy is attached to this Office Action (paper no. 9).

### **Drawings**

5) The drawings submitted in the instant application are not objected to by the Draftsperson under 37 C.F.R 1.84 or 1.152 and as such, the drawings have been approved as formal drawings.

### **Specification - Informalities**

6) The instant specification is objected to for the following reason(s):

The first paragraph of the specification does not provide information about the application

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to which priority is claimed as shown above. See section ‘Priority’ above. Amendment to the first paragraph of the specification is needed to reflect this.

**Rejection(s) under 35 U.S.C § 112, First Paragraph**

7) Claims 11-16 are rejected under 35 U.S.C. § 112, first paragraph, as failing to provide an adequate written description of the invention and failing to provide an enabling disclosure, because the specification does not provide evidence that the claimed biological material is (1) known and readily available to the public; (2) reproducible from the written description, e.g. sequenced; or (3) deposited.

Claims 11-16 are directed to a bacterial strain identified as “NRRL-B-.....”. It is apparent that this bacterial strain is required to practice the claimed invention. As a required element, the bacterial strain must be known and be readily available to the public, or obtainable by a reproducible method set forth in the specification, or otherwise be readily available to the public. If it is not so obtainable or available, the enablement requirements of 35 U.S.C. § 112, first paragraph, may be satisfied by a deposit of the bacterial strain.

From paragraph 3 on page 12 of the instant specification, it appears that each bacterial strain may have been deposited at a recognized depository in compliance with 37 C.F.R § 1.801-1.809. If the deposits have already been made under the provisions of the Budapest Treaty, filing of a signed affidavit or declaration by Applicant or assignees, or a statement by an attorney of record having a registration number who has authority and control over the conditions of deposit stating that the deposit has been accepted by an International Depository Authority under the provisions of the Budapest Treaty, that **all** restrictions upon public access to the deposit will be irrevocably removed upon the grant of a patent on this application, is required. This requirement is necessary when deposits are made under the provisions of the Budapest Treaty as the Treaty leaves this specific matter to the discretion of each state. Further, the statement should identify the deposited bacterial strain by its depository accession numbers, establish that the deposited bacterial strain is the same as the one described in the specification and that the deposited bacterial strain was in Applicant’s possession at the time of filing. As a means of satisfying the necessary criteria of the deposit rules and to show that each claimed bacterial strain is the same as

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the one deposited, Applicant may submit a copy of the contract or a notice of acceptance of each bacterial strain by the depository.

Applicants' attention is directed to *In re Lundack*, 773 F.2d. 1216, 227 USPQ 90 (CAFC 1985) and 37 C.F.R. § 1.801-1.809 for further information concerning deposit practice.

**Rejection(s) under 35 U.S.C § 112, Second Paragraph**

8) Claims 7-9 and 11-16 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention.

(a) Claim 7 is vague and indefinite in the recitation "selected from a group consisting of". To be consistent with the correct Markush language used in claim 8, it is suggested that Applicants replace the recitation with --selected from the group consisting of--.

(b) Claim 11 is vague and indefinite in the recitation: "mutants", because it is unclear what is encompassed in this limitation. What characteristics does a bacterial strain should have in order to qualify as a mutant, and what kind of mutations are encompassed is not clear.

(c) Claim 9 is vague and indefinite in the recitation: "*Corynebacterium* sp. strain". To be consistent with the language used in claim 10, it is suggested that Applicants replace the recitation with --*Corynebacterium* strain--.

(d) Claim 6 is vague and indefinite in the recitation "medium", because it is unclear what is encompassed in this limitation. The term 'medium' has several meanings. Do Applicants mean this to be a bacterial culture medium or any solvent medium?

(e) Claim 6 is confusing in the recitation "bacterial strain B selected from said mutagenized parenteral strain", because it is unclear how a strain can be selected from the parenteral strain, as opposed to a bacterial culture medium containing the parenteral strain. Clarification/correction is requested.

(f) Claim 9 is vague and indefinite in the recitation "medium", because it is unclear what is encompassed in this limitation. The term 'medium' has several meanings. Do Applicants mean this to be a bacterial culture medium or any solvent medium?

(g) Claim 11 is vague in the recitation "bacterial strain" without particularly and

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distinctly identifying the bacterial strain by its name.

(h) Claims 8 and 12-16, which depend from claim 8 and 11 respectively are also rejected as being indefinite, because of the indefiniteness identified above in the base claim.

#### **Double Patenting**

9) The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970) and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 C.F.R 1.321(c) may be used to overcome an actual or provisional rejection based on a non-statutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 C.F.R 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 C.F.R 3.73(b).

(a) Claims 6-8 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 20, 21-26, 29, 30, 49-52, 54, 57 and 58 of the co-pending application, SN 08/962,303. Although the conflicting claims are not identical, they are not patentably distinct from each other because of the overlapping scope.

(b) Claims 6-8 are rejected under the judicially created doctrine of obviousness-type double patenting over claims 1-12 of the patent, US 5,939,307. Although the conflicting claims are not identical, they are not patentably distinct from each other, because strain claimed in the instant claims are encompassed in the scope of the claims of the issued patent.

#### **Rejection(s) under 35 U.S.C § 102**

10) The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

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A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

- 11) Claims 6-8 are rejected under 35 U.S.C. § 102(b) as being anticipated by Sahm et al. (*Ann. N.Y. Acad. Sci.* 782: 25-39, 1996 - Applicants' IDS).

Claims 6-8 are product-by-process claims and are not limited to the manipulations of the recited steps, but only the structure implied by the steps. MPEP § 2113 states:

[E]ven though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process. *In re Thorpe*, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985) (citations omitted).

Sahm et al. taught a mutant *Corynebacterium glutamicum* strain that produced an amino acid, such as, L-lysine, L-threonine or L-isoleucine. The mutant strain was produced by mutagenesis. See entire document, especially section 'L-lysine-producing strains'; Figure 2 and Table 2).

Claims 6-8 are anticipated by Sahm et al.

#### Remarks

- 12) Claims 6-16 stand rejected.
- 13) Papers related to this application may be submitted to Group 1600, AU 1645 by facsimile transmission. Papers should be transmitted via the PTO Fax Center located in Crystal Mall 1. The transmission of such papers by facsimile must conform with the notice published in the Official Gazette, 1096 OG 30, November 15, 1989. The CM1 facsimile center's telephone number is (703) 308-4242, which is able to receive transmissions 24 hours a day and 7 days a week. The RightFax number for submission of before-final amendments is (703) 872-9306. The RightFax number for submission of after-final amendments is (703) 872-9307.
- 14) Any inquiry concerning this communication or earlier communications from the Examiner should be directed to S. Devi, Ph.D., whose telephone number is (703) 308-9347. A message may be left on the Examiner's voice mail system. The Examiner can normally be reached on Monday to Friday from 7.15 a.m. to 4.15 p.m. except one day each bi-week, which would be

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disclosed on the Examiner's voice mail system

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Lynette Smith, can be reached on (703) 308-3909.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

  
S. DEVI, PH.D.  
PRIMARY EXAMINER

October, 2002